Long-Acting Injectables May Be Given Once Every Other Month

Cabotegravir plus rilpivirine maintenance therapy worked equally well when taken monthly or every two months.

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A combination of two injectable antiretrovirals, cabotegravir and rilpivirine, is similarly effective at maintaining viral suppression when administered once monthly or every other month, the companies developing the long-acting regimen announced.

“The ATLAS-2M study results mean that people living with HIV could maintain viral suppression with six total treatments per year, instead of a daily oral treatment 365 times per year,” said Kimberly Smith, MD, head of global research and development at ViiV Healthcare.

Injectable formulations of ViiV’s experimental integrase inhibitor cabotegravir plus Janssen’s non-nucleoside reverse transcriptase inhibitor rilpivirine (sold in pill form as Edurant) have been studied both in people switching from standard oral antiretroviral therapy with an undetectable viral load and in those starting HIV treatment for the first time.

As reported at this year’s Conference on Retroviruses and Opportunistic Infections, results from the Phase III ATLAS trial showed that 92.5% of people randomly assigned to switch to the injectable regimen had undetectable HIV (less than 50 copies) 48 weeks later, as did 95.5% of those who stayed on their oral regimen. Likewise, the FLAIR trial saw similar rates of viral suppression in people new to treatment, 93.6% and 93.3%, respectively.

In both studies, treatment with injectable cabotegravir and rilpivirine was generally safe and well tolerated, and serious adverse events were rare. The most common side effects were injection site reactions such as pain and swelling, but these were typically mild to moderate and declined over time. Study results presented at this summer’s International AIDS Society Conference on HIV Science in Mexico City showed that people taking the injectables reported a high level of satisfaction with their treatment and preferred them to daily oral meds.

In these studies, cabotegravir and rilpivirine were administered by health care providers as two separate intramuscular injections, preferably in the buttocks. Participants were asked to return to their clinic each month within a seven-day window. Adherence was good in both studies, with almost everyone receiving monthly treatment within this window.

Nonetheless, returning to a clinic for injections every month can be inconvenient, and receiving treatment less frequently would be attractive.

The Phase III ATLAS-2M trial was a head-to-head comparison in which participants were randomly assigned to receive cabotegravir and rilpivirine injections either every four weeks or every eight weeks.

This international study included 1,045 people with HIV who were on their first or second antiretroviral regimen, had viral suppression for at least six months and had no history of prior treatment failure.

ViiV and Janssen announced in press releases that the study met its primary endpoint, showing that the efficacy of the injectable cabotegravir/rilpivirine combo was similar at 48 weeks regardless of whether it was administered once a month or every other month. In other words, cabotegravir/rilpivirine given every eight weeks was found to be noninferior to administration every four weeks.

The companies did not provide viral suppression rates or other detailed data at this time, indicating that these would be presented at an upcoming scientific conference.

“We are excited to report that for the first time since the AIDS epidemic started more than 30 years ago, our ATLAS-2M study has demonstrated that it is possible to maintain suppression of the HIV virus with an injectable regimen containing two drugs administered every two months,” Smith said. “Approval of this regimen would mark a significant change in the HIV treatment paradigm.”

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